

Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
		doxorubicin hcl	Antineoplastic Used in the treatment of various forms of cancer
		gentamicin	Antibacterial Agent (Anti-Infective Agent) Used to treat serious bacterial infections
		heparin	Anticoagulant (Cardiovascular Agent) Used to decrease the clotting ability of the blood
		sodium chloride	Flush; Abortifacient Used to remove medicine and blockage from intravenous (IV) catheter. Also used to induce abortion

### 1. Baxter Has Been the Target of Government Investigations

273. Baxter has been investigated by the United States Department of Justice, Department of Health and Human Services Office of Inspector General, the Attorney General for the State of California, the Attorney General for the State of Texas, the Attorney General for the State of Illinois, and the Committee on Commerce of the House of Representatives.

274. These investigations confirm that Baxter has engaged in a deliberate scheme to inflate AWP's for many or most of its drugs. A Baxter document made public as a result of the congressional investigation entitled, "Confidential – Baxter Internal Use Only," acknowledged that: "Increasing AWP's was a large part of our negotiations with the large homecare companies." Baxter further admitted in internal documents that homecare companies that reimburse based on AWP make a significantly higher margin. Thus, Baxter's own documents demonstrate its active participation in the scheme to artificially inflate AWP's.

2.

275

**REDACTED**

**REDACTED**

3.

276.

**REDACTED**

4.

277.

**REDACTED**

278.

**REDACTED**

## REDACTED

279. In addition, Baxter's marketing and sales documents, which were prepared and disseminated to its employees and agents via the U.S. mail and interstate wire facilities, compared the costs of their respective drugs to those of their respective competitors and were intended to induce physicians to use Baxter drugs and shift market share in its favor. Other documents created and disseminated by Baxter compared the AWP and the actual "cost" of their respective drugs, so that medical providers could easily see the different "return-to-practice" amounts available for different levels of purchase.

### **5. Specific Baxter AWP's Documented by the DOJ**

280. In a report published by the DHHS (AB-00-86), the DOJ documented at least 41 instances where the published AWP's for various dosages of drugs manufactured by Baxter were substantially higher than the actual prices listed by wholesalers. The chart below sets forth the four drugs identified by the DOJ and the spread associated with one particular dosage of each drug. These figures compare the DOJ's determination of an accurate AWP for that particular

dosage, based upon wholesalers' price lists, with the AWP reported by Baxter in the 2001 *Red Book*.

Drug in Lowest Dosage Form	Baxter's 2001 <i>Red Book</i> AWP	DOJ Determined Actual AWP	Difference	Percentage Spread
Dextrose	\$928.51	\$2.25	\$926.26	41,167%
Dextrose Sodium Chloride	\$357.69	\$2.93	\$354.76	12,108%
Sodium Chloride	\$928.51	\$1.71	\$926.80	54,199%
Factor VIII	\$1.28	\$ .92	\$ .36	39%

(P006299-006316).

6.

281.

**REDACTED**

282.

**REDACTED**

7.

283.

**REDACTED**

**REDACTED**

**Table 1**

**REDACTED**

**Table 2**

**REDACTED**

**REDACTED****8. Baxter Provided Free Goods and Other Incentives**

13. Baxter also provided physicians with free goods with the understanding that physicians would bill for those goods, in violation of federal law. Billing for free goods was a way for physicians to obtain greater profit at the expense of the Class. Baxter's fraudulent use of free goods aimed at increasing market share is evidenced by an internal memorandum from a Baxter contract administrator to certain field sales managers encouraging the distribution by U.S. mail or otherwise of free product to achieve overall price reduction:

BAXTER: "The attached notice from Quantum Headquarters was sent on April 10th to all their centers regarding the reduction on Recombinate pricing. Please note that they want to continue to be invoiced at the \$.81 price. They have requested that we send them free product every quarter calculated by looking at the number of units purchased in that quarter and the \$.13 reduction in price . . . free product given to achieve overall price reduction."

Letter from Stark, Committee on Ways and Means to Holman, Pres. Pharmaceutical Research and Manufacturers of America, Sept. 28, 2002 (P0075410-44).

285. As set forth above, Baxter's scheme to inflate its reported AWP's, market the resulting spread, and channel to providers "free" goods – all in order to increase the market share of its drugs – has resulted in excessive overpayments by Plaintiffs and the Class.

**F. Bayer**

286. Bayer engages in an organization-wide and deliberate scheme to inflate AWP's. Bayer has stated fraudulent AWP's for all or almost all of its drugs, including those set forth below. The specific drugs of Bayer for which relief is sought in this case are set forth in Appendix A, and are set forth below:

Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
--------------	-------------------------------	--------------	----------------------------

Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
BAYER	Cipro	ciprofloxacin or ciprofloxacin hcl	Antibiotic Agent (Anti-Infective Agent) Used in the treatment of various bacterial infections, including anthrax
	Cipro XR	ciprofloxacin hcl- ciprofloxacin betaine	Antibiotic Agent (Anti-Infective Agent) Used in the treatment of various bacterial infections, including anthrax
	DTIC-Dome	dacarbazine	Antineoplastic Used in the treatment of melanoma and Hodgkin's disease
	Gamimune N	immune globulin (human) iv	Immunizing Agent Used as maintenance therapy in patients with compromised immune systems
	Koate-HP	antihemophilic factor (human)	Antihemophilic Factor (Blood Modifier) Used to increase blood clotting and decrease bleeding episodes
	Kogenate	antihemophilic factor (recombinant)	Antihemophilic Factor (Blood Modifier) Used to increase blood clotting and decrease bleeding episodes
	Mithracin	plicamycin	Antineoplastic; Antihypercalcemic Agent Used in the treatment of various forms of cancer

# **1. Bayer Has Been the Target of Government Investigations**

287. In connection with its scheme to inflate AWP's, Bayer has been investigated by the Department of Justice, Department of Health and Human Services, Office of Inspector General, and the Commonwealth of Massachusetts. Bayer agreed to settle claims asserted by the United States government and 47 states arising from its fraudulent pricing and marketing practices. According to the DOJ's January 23, 2001 press release:

The government's investigation of the allegations...revealed that [Bayer] beginning in the early 1990s, falsely inflated the reported drug prices – referred to by the industry as the Average Wholesale Price (AWP), the Direct Price and the Wholesale Acquisition Cost – used by state governments to set reimbursement rates for the Medicaid program. By setting an extremely high AWP and, subsequently, selling drugs at a dramatic discount, Bayer induced physicians to purchase its products rather than those of competitors by enabling doctors to profit tremendously from reimbursement paid to them by the government.

The Bayer AWP's at issue in the investigation involved Bayer's biologic products such as Kogenate, Koate-HP, and Gamimmune, which are widely used in treating hemophilia and immune deficiency diseases. The investigation further revealed that the practice in which Bayer selectively engaged, commonly referred to as "marketing the spread," also had the effect of causing other drug companies to inflate their AWP's.

"Bayer Corporation Settlement on Medicaid Drug Prices" (P011236-011237).

288. As part of its settlement of government claims in 2000, Bayer is required, under the terms of a corporate integrity agreement, to provide state governments and the federal government with the average selling prices of its drugs – a price which accounts for all discounts, free samples, rebates and all other price concessions provided by Bayer to any relevant purchaser that result in a reduction of the ultimate cost to Bayer's customers.

289. In April 2003, Bayer also agreed to pay the government \$251.6 million in civil penalties for violating the Federal Prescription Drug Marketing Act for alleged overcharges involving its antibiotic Cipro and its high blood pressure drug Adalat.

2.

290.

**REDACTED**

**3. Bayer's AWP Manipulation Benefited Providers at the Expense of the Class**

291. As detailed in a September 28, 2000 letter from Representative Stark to Alan F. Holmer, President of the Pharmaceutical Research and Manufacturers of America, internal Bayer



documents reveal Bayer knowingly participated and directed the scheme to artificially inflate the AWP for its products and to market the spread:

BAYER: "Chris, if Baxter has increased their AWP then we must do the same. Many of the Homecare companies are paid based on a discount from AWP. If we are lowed [sic] than Baxter then the return will be lower to the HHC. It is a very simple process to increase our AWP, and can be done overnight."

(P007549.)

292. Tom Bliley, in a letter dated September 25, 2000 to the Health Care Financing Administration, analyzed drug sales in Florida and noted that sales of Bayer's WhinRho "skyrocketed" when competitors reduced their spreads but Bayer did not.

#### 4. Specific Bayer AWP's Documented by the DOJ

293. In a report published by the DHHS, the DOJ documented at least 10 instances where the published AWP's for various dosages of two drugs manufactured by Bayer were substantially higher than the actual prices listed by wholesalers. The chart below sets forth the two drugs identified by the DOJ and the spread associated with one particular dosage of each drug. These figures compare the DOJ's determination of an accurate AWP for that particular dosage, based upon wholesalers' price lists, with the AWP reported by Abbott in the 2001 *Red Book*.

Drug	Bayer's 2001 <i>Red Book</i> AWP	DOJ Determined Actual AWP	Difference	Percentage Spread
Immune Globulin	\$450.00	\$362.50	\$87.50	24%
Factor VIII	\$0.92	\$0.42	\$0.50	119%

(AB-00-86 (P006299-006316)).

294. In a DHHS OIG report (*see* OEI-03-00-00310 (P006398-006424)), the government also discovered that the AWP for all immune globulin pharmaceuticals (of a dosage of 5g), including Bayer's Gamimune® (Bayer was one of five manufacturers of the dosage listed in the 1997 *Red Book*), were over inflated by an average spread of 32.21%.

295. According to the government's settlement with Bayer arising out of Bayer's fraudulent pricing and marketing practices, the Bayer AWP's at issue in the investigation (and ultimately settled) include the AWP's for Kogenate.

**5. Inflated AWP's From Bayer's Price Lists**

296. According to Bayer's own documents, the published AWP's for its drugs were higher than the actual prices provided to wholesalers. In response to government subpoenas, Bayer produced numerous price lists setting forth spreads between AWP's and prices apparently offered to wholesalers, providers and other intermediaries. A review of those price lists reveals that Bayer has consistently offered hundreds of its drugs and other solutions to its customers at prices significantly below the published AWP and that the spread was of great importance to its customers.

**6. Bayer Provided Free Goods and Other Incentives**

297. In addition to marketing the spread, Bayer has utilized other impermissible inducements to stimulate sales of its drugs. These inducements were designed to result in a lower net cost to the provider while concealing the actual wholesale price beneath a high invoice price. By utilizing "off-invoice" inducements, Bayer provided purchasers with substantial discounts meant to gain their patronage while maintaining the fiction of a higher wholesale price.

298. Evidence of these practices is found in an October 1, 1996 Bayer internal memorandum addressing volume sales opportunities for the pharmaceutical Kogenate®:

BAYER: "I have been told that our present Kogenate price, \$.66 is the highest price that Quantum is paying for recombinant factor VIII. In order to sell the additional 12mm/u we will need a lower price. I suggest a price of \$.60 to \$.62 to secure this volume. From Quantum's stand [sic] point, a price off invoice, is the most desirable. We could calculate our offer in the form of a marketing grant, a special educational grant, payment for specific data gathering regarding Hemophilia treatment, or anything else that will produce the same dollar benefit to Quantum Health Resources."

299. As set forth above, Bayer's scheme to inflate its reported AWP's and market the resulting spread to increase the market share of its drugs and its use of other "off invoice" rebates and financial inducements to its customers has resulted in excessive overpayments by Plaintiffs and the Class.

300. Bayer routinely offered its customers off-invoice discounts as one feature of its standard contracts. (BAYM002428).

#### 7. Bayer Concealed Its AWP Manipulation

301. Bayer deliberately acted to conceal its fraudulent reporting and marketing of the AWP spread. Bayer routinely required that its customers keep secret the prices they were being charged for Bayer drugs. (BAYM000913, BAYM002436).

#### G. The Boehringer Group

302. The Boehringer Group engages in an organization-wide and deliberate scheme to inflate AWP's. The Boehringer Group has stated fraudulent AWP's for all or almost all of its drugs, including those set forth below. The specific drugs of The Boehringer Group for which relief is sought in this case are set forth in Appendix A and are identified below:

Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
BOEHRINGER GROUP (Boehringer, Ben Venue, Bedford and Roxane)	Viramune	nevirapine	Antiviral Agent (Anti-Infective Agent) Used in the treatment of HIV infection
		acycolvir sodium	Anti-Infective Agent Used in the treatment of herpes infections
		amikacin sulfate	Antibiotic Agent (Anti-Infective Agent) Used to treat respiratory tract, urinary tract, bone, skin and soft tissue infections
		cytarabine	Antineoplastic Used to treat leukemia and non-Hodgkin's lymphoma
		doxorubicin hydrochloride	Antineoplastic Used in the treatment of ovarian cancer and AIDS-related Kaposi's sarcoma

Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
		etoposide	Mitotic Inhibitor (Antineoplastic) Used in the treatment of testicular neoplasm and small cell cancer of the lung
		leucovorin calcium	Antianemic Agent (Blood Modifier) Used in the treatment of anemia
		methotrexate sodium	Antineoplastic Used in the treatment of various forms of cancer
		mitomycin	Antineoplastic Used in the treatment of various forms of cancer
		vinblastine	Antineoplastic Used in the treatment of various forms of cancer, including lymphoma and breast cancer
		vinblastine sulfate	Antineoplastic Used in the treatment of various forms of cancer, including lymphoma and breast cancer

## 1. The Boehringer Group Has Been the Target of Government Investigations

303. In connection with its scheme to inflate AWP's, The Boehringer Group has been investigated by the Department of Justice, the Department of Health and Human Services Office of Inspector General, the Committee on Commerce of the House of Representatives, and the Nevada Attorney General.

## 2. The Boehringer Group Controls the Published AWP for Its Products

304. The Boehringer Group has controlled and set the AWP's for its pharmaceutical products through direct communications with industry compendia during the Class Period. For example, a September 27, 1996 document entitled "*Red Book* Product Listing Verification" required Defendant to sign each page that contained a list of The Boehringer Group's products, NDC numbers, AWP's, WAC's and price effective dates. (MDL BV 000799). Similarly, a *Red Book* New Product Information Form dated November 25, 1996 was completed by Bedford for

the drug Ketamine Hydrochloride Injection USP and required Bedford to fill in the AWP and WAC for the product (which it did). (MDL BV 000807).

305.

**REDACTED**

**REDACTED**

306.

**REDACTED**

307. Of course, depending on which government entity was performing the investigation and the date of the government's inquiries, The Boehringer Group's "definition" of AWP changed. By November 2, 1999, Bedford told the Committee on Commerce that it understood AWP to be tied to "the manufacturer's suggested prices to customers of its customers." (MDL BV 006761-65, at 6763).

308. In a letter dated June 5, 2000 to the Nevada Attorney General regarding the Attorney General's inquiries about Bedford's AWP, Bedford responded in pertinent part:

**1. Identify what Bedford represents to be its understanding of the meaning "AWP."**

Answer: Bedford's understanding of AWP, derived from its experience in the industry, is that it is a suggested price identified by pharmaceutical companies as the price a wholesaler may wish to charge its customers for pharmaceutical products. Bedford has always viewed AWP as a suggested 'retail' price to the customers of wholesalers and not as an acquisition cost to wholesalers.

**2.**

**REDACTED**

**REDACTED**

309. In fact, even armed with the knowledge that industry compendia use Bedford's HLPs as AWP, Bedford admits that HLPs do not accurately reflect the AWP for its drugs:

As indicated above, Bedford does not communicate AWP for its products. However, it is aware that pharmaceutical price reporting services have chosen to report Bedford's HLP as AWP. Bedford has always reported its HLP accurately. *These list prices are not averages of the wholesale prices for Bedford's products.*

(MDL BV 002071-73. at 2073) (emphasis added).

310.

**REDACTED**

### **3. Specific Boehringer AWP's Documented by the DOJ**

311. In a report published by the DHHS, the DOJ documented at least 32 instances where the published AWP's for various dosages of nine drugs manufactured by The Boehringer Group were substantially higher than the actual prices listed by wholesalers. The chart below sets forth the nine drugs identified by the DOJ and the spread associated with one particular dosage of each drug. These figures compare the DOJ's determination of an accurate AWP for

that particular dosage, based upon wholesalers' price lists, with the AWP reported by The Boehringer Group in the 2001 *Red Book*.

Drug	The Boehringer Group's 2001 <i>Red Book</i> AWP	DOJ Determined Actual AWP	Difference	Percentage Spread
Acyclovir Sodium	\$ 528.00	\$ 207.00	\$ 321.00	155%
Amikacin Sulfate	\$ 437.50	\$ 65.33	\$ 372.17	570%
Mitomycin	\$ 128.05	\$ 51.83	\$ 76.22	147%
Cytarabine	\$ 62.50	\$ 3.55	\$ 58.95	1,661%
Doxorubicin HCL	\$ 945.98	\$ 139.75	\$ 806.23	577%
Etoposide	\$ 110.00	\$ 8.45	\$ 101.55	1,202%
Leucovorin Calcium	\$ 184.40	\$ 2.76	\$ 181.64	6,581%
Methotrexate Sodium	\$ 68.80	\$ 2.63	\$ 66.17	2,516%
Vinblastine Sulfate	\$ 212.50	\$ 8.19	\$ 204.31	2,495%

#### 4. Inflated Boehringer Group AWP's From Bedford's Price Lists

312. According to Bedford's own documents, the published AWP's for the drugs listed above by the DOJ were, in fact, higher than the actual prices provided to wholesalers. In response to government subpoenas, Bedford produced several price lists setting forth spreads between AWP's and prices apparently offered to wholesalers, providers and other intermediaries. A review of those price lists reveals that Bedford has consistently offered the above drugs and other solutions to its customers at prices significantly below the published AWP and that the spread was of great importance to its customers. (MDL BV 000799-806).

313. As set forth above, The Boehringer Group's scheme to inflate its reported AWP's and market the resulting spread to increase the market share of its drugs has resulted in excessive overpayments by Plaintiffs and the Class.

#### H. B. Braun

314. B. Braun engages in an organization-wide and deliberate scheme to inflate AWP's. B. Braun has stated fraudulent AWP's for all or almost all of its drugs, including those set forth



below. The specific drugs of B. Braun for which relief is sought in this case are set forth in Appendix A and identified below:

Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
B. BRAUN		dextrose	Caloric Agent; Electrolyte Replenisher Used to increase intake of calories and fluids
		dextrose in lactated ringers	Caloric Agent; Electrolyte Replenisher Used to increase intake of calories and fluids
		dextrose w/ sodium chloride	Caloric Agent; Electrolyte Replenisher Used to increase intake of calories and fluids
		heparin sodium (porcine) in d5w	Blood Modifier Used to treat and prevent thrombosis and pulmonary embolism
		sodium chloride	Flush; Abortifacient Used to remove medicine and blockage from intravenous (IV) catheter. Also used to induce abortion
		sodium chloride (gu irrigant)	Flush; Abortifacient Used to remove medicine and blockage from intravenous (IV) catheter. Also used to induce abortion

**1. B. Braun Has Been the Target of Government Investigations**

315. In connection with its scheme to inflate AWP's, B. Braun has been investigated by the United States Department of Justice, the Office of Inspector General of the Department of Health and Human Services, the Attorney General for the State of Texas, and the Attorney General for the State of California.

2.

316.

**REDACTED**

**REDACTED**

3.

317.

**REDACTED**

b.

**REDACTED**

**REDACTED**

4.

318.

**REDACTED**

319.

**REDACTED**

320.

**REDACTED**

a.

**REDACTED**

b.

**REDACTED**

321. B. Braun, through its employees and agents, also provided free samples of its drugs, and purported educational grants, to providers. The free samples and educational grants would be used to offset the total cost associated with purchases of its drugs, thereby increasing the spread, while also concealing the actual cost of the drug from Plaintiffs and the Class.

322.

**REDACTED**

**5. Specific B. Braun AWP's Documented by the DOJ**

323. In a report published by the DHHS (the "DHHS Report"), the DOJ documented at least 23 instances where the published AWP's for various dosages of 3 drugs manufactured by

B. Braun were substantially higher than the actual prices listed by wholesalers. The chart below sets forth the 3 drugs identified by the DOJ and the spread associated with one particular dosage of each drug. These figures compare the DOJ's determination of an accurate AWP for that particular dosage, based upon wholesalers' price lists, with the AWP reported by B. Braun in the 2001 *Red Book*.

Drug	B. Braun's 2001 <i>Red Book</i> AWP	DOJ Determined Actual AWP	Difference	Spread
Dextrose	\$11.28	\$1.61	\$9.67	601%
Dextrose Sodium Chloride	\$11.34	\$1.89	\$9.45	500%
Sodium Chloride	\$11.33	\$1.49	\$9.84	660%

#### 6. Inflated AWP's From B. Braun Price Lists

324. In response to government subpoenas, B. Braun produced numerous price lists setting forth spreads between AWP's and prices offered to wholesalers, providers and other intermediaries. A review of those price lists reveals that B. Braun has consistently offered drugs and other solutions to its customers at prices significantly below the published AWP and that the spread was of great importance to its customers. To repeat every one of those drugs and the spread offered to each specific customer here is not practical. However, set forth below in Table 1 are a number of those drugs (not already referenced above) and the substantial spread offered to a particular B. Braun customer.

325.

**REDACTED**

**Table 1**

**REDACTED**

326. As set forth above, B. Braun's scheme to inflate its reported AWP's and market the resulting spread to increase the market share of its drugs has resulted in excessive overpayments by Plaintiffs and the Class.

**I. The BMS Group (Bristol-Myers, OTN and Apothecon)**

327. The BMS Group has engaged in an ongoing deliberate scheme to inflate AWP's. The specific drugs for which relief is sought in this case are identified in Appendix A and are as follows:

Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
BMS GROUP (Bristol-Myers, OTN and Apothecon)	Avapro	irbesartan	Antihypertensive Agent Used to treat hypertension
	Blenoxane	bleomycin sulfate	Antineoplastic Used in the treatment of various forms of cancer
	Buspar	buspirone hcl	Antianxiety Agent (Psychotherapeutic Agent) Used to treat certain anxiety disorders or to relieve the symptoms of anxiety
	Carboplatin	paraplatin	Antineoplastic Used to treat cancer of the ovaries
	Cefzil	cefprozil	Antibacterial Agent (Anti-Infective Agent) Used in the treatment of infections caused by bacteria
	Coumadin	warfarin sodium	Anticoagulant (Blood Modifier) Used to promote clotting
	Cytosan	cyclophosphamide	Antineoplastic Used in the treatment of various forms of cancer
	Etopophos	etoposide phosphate	Antineoplastic Used to treat cancer of the testicles and certain types of lung cancer
	Glucophage	metformin hcl	Antihyperglycemic Agent Used to treat a type 2 diabetes mellitus.
	Monopril	fosinopril sodium	Antihypertensive Agent; Vasodilator (Cardiovascular Agent) Used to treat hypertension
	Monopril HCT	fosinopril sodium & hydrochloro-thiazide	ACE Inhibitor (Cardiovascular Agent) Used in the treatment of hypertension and congestive heart failure
	Plavix	clopidogrel bisulfate	Antithrombotic Agent Used to lessen the chance of heart attack or stroke

Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
	Rubex	doxorubicin hcl	Antineoplastic Used in the treatment of various forms of cancer
	Serzone	nefazodone hcl	Antidepressant (Psychotherapeutic Agent) Used to treat mental depression
	Taxol	paclitaxel	Antineoplastic Used in the treatment of various forms of cancer
	Tequin	gatifloxacin	Antibacterial Agent (Anti-Infective Agent) Used to treat bacterial infections
	Vepesid	etoposide	Antineoplastic Used to treat cancer of the testicles and certain types of lung cancer
	Videx EC	didanosine	Antiviral Agent (Anti-Infective Agent) Used in the treatment of HIV infection
		amikacin sulfate	Antibiotic Agent (Anti-Infective Agent) Used to treat respiratory tract, urinary tract, bone, skin and soft tissue infections
		amphotercin b	Antifungal Agent (Anti-Infective Agent) Used to help the body overcome serious fungus infections

**1. The BMS Group Has Been the Target of Government Investigations**

328. In connection with its scheme to inflate AWP's, BMS has been investigated by the United States Department of Justice, Commonwealth of Massachusetts, Office of Inspector General of the U.S. Department of Health and Human Services, Attorney General for the State of Texas, State of California Department of Justice Office of the Attorney General, State of California Department of Justice, Bureau of Medi-Cal Fraud and Elder Abuse, and the U.S. House of Representatives, Committee on Commerce. Defendant Apothecon has been investigated in connection with its scheme to inflate AWP's by at least the Office of Medicare Fraud and Elder Abuse, Office of Attorney General, State of Texas.

329. These investigations confirm that BMS engaged in an ongoing deliberate scheme to inflate AWP's. For example, by letter dated February 27, 2001 to BMS, Rep. Stark outlined numerous examples of illegal practices by BMS. Referring to a letter from Denis Kaszuba, a

senior pricing analyst at BMS to Medispan, dated August 10, 1992 (BMSAWP/0011247), Rep.

Stark noted:

Bristol has control over the AWP, DP, and WACs published for its drugs and directs national publishers to change their prices. Bristol directed a national publisher of drug prices to increase all of Bristol's AWP for oncology drugs by multiplying Bristol's supplied direct prices by a 25% factor rather than the previous 20.5% factor . . . The increase in the AWP created a spread that, in itself, provided a financial kickback to oncologists for prescribing Bristol's cancer drugs.

330. In the same letter, Rep. Stark noted:

The evidence clearly shows that Bristol has intentionally reported inflated prices and has engaged in other improper business practices in order to cause its customers to receive windfall profits from Medicare and Medicaid when submitting claims for certain drugs. The evidence further reveals that Bristol manipulated prices for the express purpose of expanding sales and increasing market share of certain drugs where the arranging of a financial benefit or inducement would influence the decisions of healthcare providers submitting the Medicare and Medicaid claims.

## **2. The BMS Group Controls the Published AWP for Its Products**

331. The BMS Group has controlled and set the AWP for its pharmaceutical products through direct communications with industry compendia during the Class Period. In one BMS document, Denise Kaszuba, a senior BMS Group pricing analyst, instructed the *Red Book* that:

Effective immediately, Bristol-Myers Oncology Division products factor used in determining the AWP should be changed from 20.5% to 25%. This change should not effect [sic] any other business unit of Bristol-Myers Squibb Company.

332. Other internal documents clearly indicate that BMS had direct control over the spread between its states wholesale price and the published AWP. A BMS office dispatch dated September 9, 1992 notes the need for a mark up of the AWP over the state wholesale price. "After reviewing the results of the wholesaler survey performed by Bristol Oncology . . . we have determined that for those items with a labeler 0003, we will use a 1.25 mark-up and for those



items with the labeler 00015, we will use a 1.20 mark-up. We noticed too, that FDB and Redbook use a 1.20 for everything.” (BMSAWP/0011246).

**3. BMS’s AWP Manipulation Benefited Providers at the Expense of the Class**

333. BMS was well aware that providers and other purchasers of its drugs were using the spread to determine whether to purchase its drugs. Indeed, BMS was aware of and tracked the prices and AWP’s of its competitors in order to remain competitive. In an internal BMS memorandum, BMS identifies its competitors who sell etoposide (Gensia, Pharmacia, Abbott, Chiron, Ben Venue, Immunex and Astra) and their corresponding list price and AWP’s. (BMS3CA/000128).

334. BMS created AWP competitor analyses that tracked the AWP’s of its competitors’ relevant drugs, and used that data internally to propose suggested AWP’s for BMS drugs. One such competitor analysis set forth the competitor AWP’s for Atenolol with chlorthalidone and provided an “Apothecon suggested AWP” for each dosage. (BMS3CA/000648)

335. BMS clearly believed that the maintenance of a spread on its drugs was important in gaining and maintaining market share. In an internal BMS document, concerning its drug Vepacid (etoposide), BMS noted:

The Etopophos product file is significantly superior to that of etoposide injection . . . . Currently, physician practice can take advantage of the growing disparity between Vepesid’s list price (and, subsequently, the Average Wholesale Price) and the actual acquisition cost when obtaining reimbursement for etoposide purchases. If the acquisition price of Etopophos is close to the list price, the physician’s financial incentive for selecting the brand is largely diminished.

**4. Specific BMS AWP’s Documented by the DOJ**

336. In a report published by the DHHS, the DOJ documented numerous instances where the published AWP’s for various dosages of five (5) drugs manufactured by the BMS Group were substantially higher than the actual prices listed by wholesalers. The chart below sets forth the BMS Group drugs identified by the DOJ and the spread associated with one

particular dosage of each drug. These figures compare the DOJ's determination of an accurate AWP for that particular dosage, based upon wholesalers' price lists, with the AWP reported by the BMS Group in the 2001 *Red Book*.

Drug	Manufacturer	BMS's 2001 <i>Red Book</i> AWP	DOJ Determined Actual AWP	Difference	Percentage Spread
Amikacin Sulfate	Apothecon	\$32.89	\$17.31	\$15.58	90%
Amphotercin B	Apothecon	\$17.84	\$6.20	\$11.64	188%
Bleomycin Sulfate	BMS	\$609.20	\$509.29	\$99.91	20%
Cyclophosphamide	BMS	\$102.89	\$45.83	\$57.06	125%
Etoposide (Vepesid)	BMS	\$136.49	\$34.30	\$102.19	298%

337. Other sources reveal additional evidence of fraudulent AWP's for drugs manufactured and marketed by the BMS Group:

**5. Other AWP's Related to VEPESID (etoposide)**

338. The February 27, 2001 letter from Rep. Stark to BMS noted that as to BMS "... the manipulated discrepancies between [BMS's] inflated AWP's and DP's versus their true costs are staggering. For example, in the 2000 edition of the *Red Book*, Bristol reported an AWP of \$1296.64 for ... Vepesid (Etoposide) for injection ... while Bristol was actually offering to sell the exact same drug to [a large national group purchasing organization] for \$70.00." The difference noted by Rep. Stark represents a % 1,752 spread related to Vepesid.

**6. Other AWP's Related to Blenoxane**

339. BMS internal documents reveal that in 1995, BMS set the *Red Book* AWP for Blenoxane at \$276.29. At the same time, BMS was selling Blenoxane to oncologists practicing in St. Petersburg, Florida for only \$224.22. In 1996, BMS increased its reported AWP for Blenoxane to \$291.49, while continuing to sell the drug to oncologist for \$224.27. In 1997, BMS falsely reported that it had increased the AWP of Blenoxane to \$304.60, when in reality, BMS had lowered the price to oncologists to \$155.00. In 1998, BMS again reported a false AWP for Blenoxane of \$304.60 while further reducing the actual price to oncologists to \$140.00.

## 7. The BMS Group Provided Free Goods and Other Incentives

340. As part of its scheme the BMS Group also used free drugs and other goods to encourage participation by physicians. Thus, for example, the BMS Group provided free Etopophos® to two Miami oncologists in exchange for their agreement to purchase other BMS Group cancer drugs. Similarly, other documents show that the BMS Group provided free Cytogards in order to create a lower-than-invoice cost to physicians that purchased other cancer drugs through OTN. (A Cytogard is a device that prevents spillage of intravenous administered treatments such as BMS's cancer drug Etopophos®.)

341. As set forth above, the BMS Group's scheme to inflate its reported AWP's, market the resulting spread, and channel to providers "free" goods – all in order to increase the market share of its drugs – has resulted in excessive overpayments by Plaintiffs and the Class.

342. For example, in a report published by DHHS, the DOJ documented at least 12 instances where the published AWP's for drugs manufactured by the BMS Group were substantially higher than the actual prices listed by wholesalers.

343. The chart below sets forth five examples where the BMS Group deliberately inflated AWP's that it reported for BMS Group drugs. These figures compare the DOJ's determination of an accurate AWP, based upon wholesalers' price lists, with the AWP reported by the BMS Group in the 2001 *Red Book*.

Drug	Manufacturer	BMS's 2001 <i>Red Book</i> AWP	DOJ Determined Actual AWP	Difference	Percentage Spread
Amikacin Sulfate	Apothecon	\$32.89	\$17.31	\$15.58	90%
Amphotercin B	Apothecon	\$17.84	\$6.20	\$11.64	188%
Bleomycin Sulfate	BMS	\$609.20	\$509.29	\$99.91	20%
Cyclophosphamide	BMS	\$102.89	\$45.83	\$57.06	125%
Etoposide (Vepesid)	BMS	\$136.49	\$34.30	\$102.19	298%

344. In 1997, an OIG Report identified three other Medicare Part B drugs with inflated AWP's – which the 1997 *Red Book* indicates were manufactured only by the BMS Group at that

time: Paraplatin® (carboplatin), Rubet® (doxorubicin hydrochloride), and Taxol® (paclitaxel). Sales of these inflated drugs were substantial. For example, Paclitaxel generated \$941 million in revenue for the BMS Group in 1997, and Carboplatin generated \$702 million in revenue in 2001.

345. The government's investigation uncovered other drugs for which the BMS Group was stating a fraudulent AWP. Specifically:

- a. In the 2000 edition of the *Red Book*, BMS reported an AWP of \$1296.64 for Vepesid (Etoposide) for injection while BMS was actually offering to sell the exact same drug to a large customer for only \$70.00.
- b. From 1995 through 1998 the *Red Book* listed AWP for BMS' Blenoxane 15u increased from \$276.29 to \$304.60, while the actual cost to physicians declined from \$224.22 to \$140.00, resulting in a spread of \$164.60 in 1998

346. An internal BMS Group document shows that the AWP set by the BMS Group for its drugs bears no relation to an *actual* wholesale price, and is greater than the highest price actually paid by providers. More specifically, in a discussion about lowering Vepesid's AWP in order to create sales for Etopophos, the BMS Group stated that the "AWP for Vepesid would be reduced from its current level to the highest bid price currently in the marketplace."

347. BMS Group documents also reveal that physicians were making medical decisions based on how much profit they could make from the AWP manipulated spread. In considering provider choice between BMS drugs Etopophos® and Vepesid® (Etoposide), the BMS Group noted that:

The Etopophos product file is significantly superior to that of etoposide injection . . . . Currently, physician practice can take advantage of the growing disparity between Vepesid's list price (and, subsequently, the Average Wholesale Price) and the actual acquisition cost when obtaining reimbursement for etoposide purchases. If the acquisition price of Etopophos is close to the list price, the physician's financial incentive for selecting the brand is largely diminished.

348. While the BMS Group and other Defendants have placed the blame for setting published AWP's on the publications in which the AWP's are contained, another BMS Group

document demonstrates that publications reporting AWP had no discretion to set AWP, and instead published verbatim the prices reported by the BMS Group and other Defendants. In the document, Denise Kaszuba, a senior BMS Group pricing analyst, instructed the *Red Book* that:

Effective immediately, Bristol-Myers Oncology Division products factor used in determining the AWP should be changed from 20.5% to 25%. This change should not effect [sic] any other business unit of Bristol-Myers Squibb Company.

**J. Dey**

349. Dey engages in an organization-wide and deliberate scheme to inflate AWP.

Dey has stated fraudulent AWP for all or almost all of its drugs, including those set forth below. The specific drugs of Dey for which relief is sought in this case are set forth in Appendix A, and are identified below:

Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
DEY		acetylcysteine	Mucolytic (Respiratory Agent: Diagnostic Aid) Used for certain lung conditions when increased amounts of mucus make breathing difficult
		albuterol or albuterol sulfate	Bronchodilator (Respiratory Agent) Used for relief of bronchospasm in asthma sufferers
		cromolyn sodium	Antiallergic and Mast Cell Stabilizer Used to help prevent or treat the symptoms of seasonal or chronic allergic rhinitis
		ipratropium bromide	Bronchodilator (Respiratory Agent) Used for relief of bronchospasm in asthma sufferers
		metaproterenol sulfate	Bronchodilator (Respiratory Agent) Used for relief of bronchospasm in asthma sufferers

**1. Dey Has Been the Target of Government Investigations**

350. In connection with its scheme to inflate AWP, Dey has been investigated by the United States Department of Justice, United States Department of Health and Human Services, Office of Inspector General, the United States District Attorney for the District of Massachusetts,

the Attorney General of the State of California, the Attorney General for the State of Texas, the Attorney General of the State of Connecticut, and the District Attorney for the County of Suffolk, New York State.

351. These investigations confirm that Dey has engaged in a deliberate scheme to inflate the published AWP for many of its drugs. For instance, Dey's spread for albuterol sulfate, a drug that constituted 37 % of Dey's income in 1998, drastically increased between 1992 and 1998. In 1992, Dey's *Red Book* AWP for albuterol sulfate (.083% concentration, 3 ml) was \$32.30. McKesson's wholesale price for the drug was \$25.45 (a spread of \$ 6.85 or 27%). By 1998, Dey's *Red Book* AWP for the same concentration/dose of albuterol sulfate had barely slipped to \$30.25, while McKesson's wholesale price had plummeted to \$10.00 (a spread of \$20.25 or 202%). See September 25, 2000 letter from U.S. Rep. Bliley to Nancy-Ann Min DeParle.

352. The federal government is not the only entity to uncover Dey's scheme to inflate AWP. The Attorneys General of Texas and West Virginia recently discovered that due to over inflated AWP, both state's Medicaid Programs have been defrauded by Dey for millions of dollars. Texas alleges that, between 1995 and 1999, it paid \$13.7 million for Dey's albuterol sulfate and ipratropium bromide, when it should have paid only \$8.7 million – an overcharge of \$5 million. West Virginia alleges that Dey and others manipulated the AWP to significantly overcharge state agencies and residents for several drugs, including albuterol, from at least 1995 through 2000.

353. In its own suit against Dey and other pharmaceutical manufacturers for AWP manipulation, the Attorney General for the State of Connecticut documented significant spreads between Dey's published AWP and actual wholesale prices for many of its drugs. Incorporated below are examples cited by the Connecticut Attorney General:

Drug	NDC #	Year	AWP	ACTUAL PRICE	SPREAD	% OVERCHARGE
ALBUTEROL	49502-0303-17	1996	\$21.70	\$3.25	\$18.45	488%
IPATROPIUM BROMIDE	49502-0685-03	2001	\$44.10	\$8.35	\$35.58	355%
IPATROPIUM BROMIDE	49502-0685-03	2000	\$44.10	\$11.45	\$32.65	239%
IPATROPIUM BROMIDE	49502-0685-03	1999	\$44.10	\$11.45	\$30.11	177%

2.

354.

**REDACTED**

a.

**REDACTED**

b.

**REDACTED**

**REDACTED**

**3. Dey's AWP Manipulation Benefited Providers at the Expense of the Class**

355. The purpose of Dey's AWP manipulation was to increase the spread in order to maximize the profit to providers and other intermediaries. This is clear from Dey's own documents. For example:

a. Dey was aware that its customers were "spread shopping" and competed by increasing the spread to its customers. In an internal worksheet filled out by Dey in preparation for a bid of potential sales to one of its customers, Dey listed the current contract price of various products as well as a recommended new contract price. In the notes next to these figures the worksheet states, "This account needs AWP-40% or better to see profit due to the employer groups they serve. Have not made the switch to our product line due to the spread . . ." (DL-TX-0014029)

b. Competition between generic products produced by Dey was fierce and the spread was a major factor in this competition. In another similar bid price worksheet for a different customer, the corresponding notes state "cromolyn pricing is at AWP-40% and 35% respectively – bear in mind that we are competing with the branded spread and the generic perception of [sic] everything should be AWP-60%" (DL-TX-0014439)

356. This competition came at the expense of Plaintiffs and the Class whose payments were based on AWP. For instance, Albuterol sulfate, a multisource drug and one of Dey's top selling products, was a focus of the federal government's investigation into AWP inflation. OIG found that "Medicare's reimbursement amount for albuterol was nearly six times higher than the median catalog price" and that "Medicare and its beneficiaries would save between \$226 million and \$245 million a year if albuterol were reimbursed at prices available to suppliers." See "Excessive Medicare Reimbursement for Albuterol," OEI-03-01-00410, March 2002.



357. The OIG determined that the Medicare-allowed amount for albuterol sulfate in 1996 was \$0.42. However the actual wholesale price was \$0.15, and the highest available wholesale price was \$0.21.

358. GAO also found that albuterol sulfate was one of a small number of products that accounted for a large portion of Medicare spending and volume. More specifically, albuterol sulfate ranked first in volume of units covered by Medicare, accounting for 65.8% of total units reimbursed. Furthermore, albuterol sulfate accounted for 6.3% of total Medicare spending, ranking fifth out of more than 400 covered drugs. See GAO Report to Congressional Committees, MEDICARE: Payments for Covered Outpatient Drugs Exceed Providers' Cost, Tables 1 and 2, pp. 7-8.

#### 4. Specific Dey AWP's Documented by the DOJ

359. In a report published by the DHHS, the DOJ documented at least 15 instances where the published AWP's for various dosages of 4 drugs manufactured by Dey were substantially higher than the actual prices listed by wholesalers. The chart below sets forth the drugs identified by the DOJ and the spread associated with one particular dosage of each of the 4 drugs. These figures compare the DOJ's determination of an accurate AWP for that particular dosage, based upon wholesalers' price lists, with the AWP reported by Dey in the 2001 *Red Book*.

Drug in Lowest Dosage Form	2001 <i>Red Book</i> AWP	DOJ Determined AWP	Difference	Percentage Spread
Acetylcysteine	\$59.88	\$25.80	\$34.08	132%
Albuterol Sulfate	\$30.25	\$9.17	\$21.08	230%
Cromolyn Sodium	\$42.00	\$23.01	\$18.99	82%
Metaproterenol Sulfate	\$30.75	\$11.29	\$19.46	172%

#### 5. Inflated Dey AWP's From Dey's Price Lists

360. According to Dey's own documents, the published AWP's for many of its own products were higher than the actual prices charged wholesalers and other intermediaries.

Table 1 below is excerpted from a pricing proposal by Dey to McKesson Drug Company, one of the county's largest wholesalers, dated December 20, 1995.

**Table 1**

Generic Name	Strength	Size	AWP	WAC	Suggested Sell Price	% Discount from WAC	% Spread
Acetylcysteine Solution	10%	4 mL	\$67.80	\$25.80	\$18.00	-40.0%	277%
Acetylcysteine Solution	10%	10 mL	\$40.26	\$15.27	\$13.50	-30.0%	198%
Acetylcysteine Solution	10%	30 mL	\$110.48	\$41.97	\$33.50	-35.0%	230%
Acetylcysteine Solution	20%	4 mL	\$81.36	\$31.08	\$21.50	-40.0%	278%
Acetylcysteine Solution	20%	10 mL	\$48.66	\$18.57	\$16.20	-30.0%	200%
Acetylcysteine Solution	20%	30 mL	\$133.43	\$50.64	\$39.90	-35.0%	234%
Acetylcysteine Solution	20%	100 mL	\$92.21	\$75.90	\$59.90	-40.0%	54%
Albuterol Sulfate Inhalation Soln.	0.083%	3 mL	\$30.25	\$14.50	\$12.00	-29.3%	152%
Albuterol Sulfate Inhalation Soln.	0.083%	3 mL	\$36.30	\$17.40	\$14.40	-29.3%	152%
Albuterol Sulfate Inhalation Soln.	0.083%	3 mL	\$72.60	\$34.50	\$28.80	-28.7%	152%
Cromolyn Sodium Inhalation, USP	20 mg/2ml	2 mL	\$42.00	\$34.20	\$29.00	-25.0%	45%
Cromolyn Sodium Inhalation, USP	20 mg/2ml	2 mL	\$84.00	\$66.00	\$58.00	-22.3%	45%
Metaproterenol Sulfate Inhalation Soln.	0.4%	2.5 mL	\$30.75	\$11.00	\$10.00	-21.5%	207%
Metaproterenol Sulfate Inhalation Soln.	0.6%	2.5 mL	\$30.75	\$11.00	\$10.00	-21.5%	207%
Sodium Chloride Solution	0.9%	3 mL	\$24.20	\$13.00	\$10.94	-32.7%	121%
Sodium Chloride Solution	0.9%	5mL	\$24.20	\$13.00	\$10.94	-32.7%	121%

(DL-TX 0011179)

#### 6. Dey Provided Free Goods and Other Incentives

361. In addition to marketing the spread, Dey has utilized other impermissible inducements to stimulate sales of its drugs without accounting for them in its WAC or AWP. These inducements were designed to result in a lower net cost to the provider while concealing the actual wholesale price beneath a high invoice price. By utilizing "off-invoice" inducements, Dey provided purchasers with substantial discounts meant to gain their patronage while maintaining the fiction of a higher wholesale price.

362. For example, in an announcement of a special incentive program to its customers to induce the purchase of its Ipratropium Bromide Inhalation solution, Dey sent its customers an offer sheet entitled "Profitability Enhancement For You" in which it stated "For every dollar of Dey Cromolyn Sodium unit-dose purchased, Dey will provide free goods of either: Coromolyn Sodium Inhalation Solution 0.02%, 2.5ml, at 1.0 times the rebate amount -OR- Ipratropium Bromide Inhalation Solution 0.02%, 2.5ml, when it launches, at a value of 1.5 times the rebate amount for Cromolyn." (DL-TX-0004775).

**7. Dey Has Concealed Its AWP Manipulation**

15. In an effort to conceal the existence of a spread from end payors, Dey concealed the true wholesale prices of its drugs. For instance, in a handwritten memorandum to Dey's pricing committee a potential pricing structure with a customer was discussed:

"I met with IPC to discuss our contract offer (illegible). . . Tom Konnelly (IPC) said he wanted to keep net pricing hidden from 3<sup>rd</sup> parties by increasing in the purchase price on our offer by 25%. IPC then requires a 25% rebate back to IPC. . . I have remarked the pricing. If this offer is accepted, the higher price will go into McKesson as a chargeback contract. Dey will then rebate IPC 25% on contract purchases on a quarterly basis. . ."

(DL-TX-0024844)

363. As set forth above, Dey's scheme to inflate its reported AWP's and market the resulting spread to increase the market share of its drugs and its use of other "off invoice" rebates and financial inducements to its customers has resulted in excessive overpayments by Plaintiffs and the Class.

**K. The Fujisawa Group (Fujisawa Pharmaceutical, Fujisawa Healthcare, Fujisawa USA)**

364. Fujisawa engages in an organization-wide and deliberate scheme to inflate AWP's. Fujisawa has stated fraudulent AWP's for all or almost all of its drugs, including those set forth below. The specific drugs of Fujisawa for which relief is sought in this case are set forth in Appendix A and are identified as follows:

Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
FUJISAWA GROUP (Fujisawa Healthcare, Fujisawa Pharmaceutical and Fujisawa USA)	Aristocort	triamcinolone, triamcinolone diacetate or triamcinolone acetonide	Anti-Inflammatory, Steroidal; Used in the treatment of asthma
	Aristospan	triamcinolone hexacetonide	Anti-Inflammatory Agent, Steroidal Used to provide relief for inflamed areas of the body
	Cefizox	ceftizoxime sodium or ceftizoxime in d5w	Antibiotic Agent (Anti-Infective Agent) General antibiotic
	Cyclocort	amcinonide	Anti-Inflammatory Agent Used to treat inflammatory symptoms of skin disorders
	Lyphocin	vancomycin hydrochloride	Antibacterial Agent Used to treat infections in many different parts of the body
	Nebupent	pentamidine isothionate	Antiprotozoal Agent Used to try to prevent Pneumocystis carinii pneumonia
	Pentam 300	pentamidine isethionate	Anti-Infective Agent Used in the treatment of pneumonia
	Prograf	tacrolimus	Immunosuppressant Used to lower the body's natural immunity in patients who receive organ transplants
		acyclovir sodium	Antiviral Agent Used to treat herpes simplex infections, varicella-zoster (chickenpox) in people with weakened immune systems, and severe genital herpes infections
		dexamethasone sodium phosphate	Anti-Inflammatory Agent; Antiemetic (Gastrointestinal Agent) Used in various applications to treat inflamed areas of the body
		doxorubicin hydrochloride	Antineoplastic Used in the treatment of ovarian cancer and AIDS-related Kaposi's sarcoma
		fluorouracil	Antineoplastic Used to treat cancer, including colon, rectum, breast, stomach, and pancreas
		gentamicin sulfate	Antibacterial Agent Used to treat serious bacterial infections
		vinblastine sulfate	Antineoplastic Used in the treatment of various forms of cancer, including lymphoma and breast cancer

**1. Fujisawa Has Been the Target of Government Investigations**

365. In connection with its scheme to inflate AWP, Fujisawa has been investigated by the United States Department of Justice, the Office of Inspector General of the Department of Health and Human Services, the Attorney General for the State of Texas, and the Attorney General for the State of California.

**2. Fujisawa Controls the Published AWP for Its Products**

366. Fujisawa controlled and set the AWP for its pharmaceutical products through direct communications with industry compendia during the Class Period. For example, on March 10, 1997, Fujisawa provided MediSpan with an updated listing of pack prices – including AWP – for all of its products. (FJ-MDL 015152-015159).

**3.**

367.

**REDACTED**

368.

**REDACTED**

369.

**REDACTED**

370.

**REDACTED**

**4. Specific Fujisawa AWP's Documented by the DOJ**

371. In a report published by the DHHS (AB-00-86), the DOJ documented at least 35 instances where the published AWP's for various dosages of 6 drugs manufactured by Fujisawa were substantially higher than the actual prices listed by wholesalers. The chart below sets forth

the 6 drugs identified by the DOJ and the spread associated with one particular dosage of each drug. These figures compare the DOJ's determination of an accurate AWP for that particular dosage, based upon wholesalers' price lists, with the AWP reported by Fujisawa in the 2001 *Red Book*.

Drug	The Fujisawa Group's 2001 <i>Red Book</i> AWP	DOJ Determined Actual AWP	Difference	Percentage Spread
Acyclovir Sodium	\$565.10 <sup>2</sup>	\$371.50	\$193.60	52%
Dexamethasone Sodium Phosphate	\$1.04 <sup>3</sup>	\$.66	\$.38	58%
Fluorouracil	\$2.87	\$1.20	\$1.67	139%
Gentamycin Sulfate	\$12.64 <sup>4</sup>	\$5.40	\$7.24	134%
Pentamidine Isethionate	\$98.75	\$36.00	\$62.75	174%
Vancomycin Hydrochloride	\$10.97 <sup>5</sup>	\$7.00	\$3.97	57%

(P006299-006316).

#### 5. Inflated AWP's From Fujisawa Price Lists

372. In response to government subpoenas, Fujisawa produced numerous price lists setting forth spreads between AWP's and prices offered to wholesalers, providers and other intermediaries. A review of those price lists reveals that Fujisawa has consistently offered drugs and other solutions to its customers at prices significantly below the published AWP and that the spread was of great importance to its customers. To repeat every one of those drugs and the spreads offered to each specific customer here is not practical.

373.

**REDACTED**

<sup>2</sup> Calculation based on the AWP listed in the 1998 *Red Book*.

<sup>3</sup> Calculation based on the AWP listed in the 1998 *Red Book*.

<sup>4</sup> Calculation based on the AWP listed in the 1998 *Red Book*.

<sup>5</sup> Calculation based on the AWP listed in the 1998 *Red Book*.

**Table 1**

**REDACTED**

374.

**REDACTED**

**Table 2**

**REDACTED**